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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/479,467      | 01/06/2000  | Paul W Sternberg     | CIT1520-1           | 3063             |

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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                  |
|------------------------------|-----------------|------------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)     |
|                              | 09/479,467      | STERNBERG ET AL. |
| Examiner                     | Art Unit        |                  |
| Peter Paras, Jr.             | 1632            |                  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 22,26 and 93-95 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 22,26 and 93-95 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 04 March 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other:

Applicant's amendment received on 3/4/03 has been entered. Claims 22, 26, and 93-95 have been amended. Claims 22, 26, and 93-95 are pending and are under current consideration.

***Drawings***

The corrected drawings filed on 3/4/03 have been approved by the Examiner.

Upon further consideration the following are new grounds of rejection under 35 U.S.C. 112, 1<sup>st</sup> paragraph as set forth below:

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 26 and 93-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for

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purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

The specification has disclosed a nucleotide sequence as set forth in SEQ ID NO: 3 that encodes a LOV-1 protein and a nucleotide sequence that encodes a mutant LOV-1 protein, the amino acid sequence of which is set forth in SEQ ID NO: 15. However, the other nucleotide sequences that encode LOV-1 proteins and are fully complementary to at least one of the exons set forth in SEQ ID NO: 3 under conditions of at least moderate stringency encompassed within the genus of LOV-1 encoding nucleotide sequences have not been disclosed. Based upon the prior art there is expected to be sequence variation among the species of cDNA encoding LOV-1, which are fully complementary to at least one of the exons set forth in SEQ ID NO: 3 under conditions of at least moderate stringency encompassed by the claims. The specification disclosed the nucleotide sequence set forth in SEQ ID NO: 3, which encodes a LOV-1 protein, and a nucleotide sequence that encodes the mutant LOV-1 protein having the amino acid sequence as set forth in SEQ ID NO: 15. The specification however has not disclosed the sequences of any of the DNA molecules, which encode LOV-1 proteins as embraced by the claims. There is no evidence on the record of a relationship between the structures of the DNA molecules encoding LOV-1 proteins that would provide any reliable information about the structure of DNA molecules within the genus. There is no evidence on the record that the nucleotide

sequences which encode LOV-1 proteins had known structural relationships to each other; the art indicated that there is variation between DNA sequences encoding LOV-1 proteins that are fully complementary to at least one of the exons set forth in SEQ ID NO: 3 under conditions of at least moderate stringency. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the claimed embodiments of the DNA molecules, other than the nucleotide sequence set forth in SEQ ID NO: 3 or the nucleotide sequence that encodes the mutant LOV-1 protein having the amino acid sequence set forth in SEQ ID NO: 15, that encode LOV-1 proteins encompassed within the genus lack a written description. The specification fails to describe what other DNA molecules fall into this genus and it was unknown as of Applicant's effective filing date that any of these DNA molecules would have the property of directing normal location of vulva and response male nematode sensory behaviors. The skilled artisan cannot envision the detailed chemical structure of the encompassed DNA molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a

mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of nucleotide sequences encoding LOV-1 proteins, other than the nucleotide sequence set forth in SEQ ID NO: 3 or the nucleotide sequence that encodes the mutant LOV-1 protein having the amino acid sequence set forth in SEQ ID NO: 15. Moreover, the art has recognized that there would be variation among the species of the genus of DNA molecules that encode LOV-1 proteins and are fully complementary to at least one of the exons set forth in SEQ ID NO: 3 under conditions of at least moderate stringency. Therefore, Applicant was not in possession of the genus of DNA molecules that encode LOV-1 proteins as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

***Allowable Subject Matter***

The subject matter of the claims with respect to parts (a) and (b) appears to be allowable.

**Conclusion**

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

**PETER PARAS  
PATENT EXAMINER**

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